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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/246,307	02/08/99	KOZIKOWSKI	A 9928-0009-99

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HM12/0117

EXAMINER

GUPTA, A

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 01/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/246,307

Applicant(s)
Kozikowski et al.

Examiner
ANISH GUPTA

Group Art Unit
1653



☒ Responsive to communication(s) filed on Oct 23, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 12-17, 20-28, 31, 32, and 73-81 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 12-17, 20-28, 31, 32, and ⁷³~~24~~-81 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Applicants amendment filed 10-23-00 is hereby acknowledged. Applicants canceled claims 1-11, 18, 19, 20, 29, 30, and 33-72, amended claims 12-13 and 22, and added claims 73-81.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-17, 20-28, 31-32 and 74-81 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants argue that "A disclosure, as filed, is presumed to be enabled, unless there is reason to objectively doubt the truth of the statement relied on for enabling support." Applicants contend that the Examiner has not provided any explanation for why claims 23-28 and 31-32, drawn to a method of enhancing cognitive function, are not enabled by the specification. The specification provides guidance on how to make the compounds and provides guidance for method of testing compounds with art recognized models that demonstrate the cognition enhancing properties of the compounds. Applicants further assert "that the conclusion and opinions of the prior art are irrelevant, since Examples 8 and 9 of the instant Application demonstrate efficacy of the compound of the invention in art-accepted animal models. Nothing more is required under 35 U.S.C. § 112, first paragraph." Finally Applicants are contending that "Applicants are entitled to a generic claim without exemplifying every possible embodiment of that generic claim." Applicants have also submitted a declaration by Dr. Alan Faden in which it is stated, when making reference to assay method used to demonstrate enhanced cognitive function, that "these assays, alone, demonstrate a high likelihood that the disclosed compounds may be useful as a cognitive enhancing therapy for indication such as Alzheimer's disease." The declaration also states that ample guidance has been provided in the specification and further provides in vitro evidence in the affidavit showing that the compounds of the claimed invention block neural cell death after insults and in vitro model of ischemia(stroke)-oxygen deprivation and excitotoxic (glutamate-induced) free radical induced injuries. In the

declaration, Dr. Faden also states, on page 4, that "[t]he claims in the accompanying response have been modified to reflect the fact that we only claim head injuries, spinal cord injury, and stroke."

Applicant's arguments filed 10-23-00 and the Declaration by Dr. Faden have been fully considered but they are not persuasive.

First, as to the scope of the claims, the claims state a method of treating a neurological disorder or a CNS injury, said method comprising the step of administering an effective amount of compound of claim 12. The claims are broad in terms of the treatment of the neurological disorders and thus are inclusive of disorders such as ALS, Parkinson's, Alzheimer's. The claims are not solely limited to head injuries, spinal cord injury, and stroke as Applicants contend. If Applicants intend such limitation, then Applicants are requested to amend the claims accordingly.

It is still the position that the specification does not provide ample guidance to the practice of the claimed invention. First the working examples provided in the declaration are drawn to the treatment of free radical and oxygen deprivation injuries. The art recognizes that neural cells can and do recover from such disorders. However, the specification nor the declaration provides any guidance as to the neuroprotection from disorders such as Alzheimer's, Parkinson's, and ALS. Applicants argue that the Examiner has not provided any evidence that the method claimed is not enabled. However, in the previous office action the reference of Patel was cited to indicate the state of the art for therapies in the treatment of Alzheimer's. The reference concludes, even after reviewing various known Alzheimer therapies, that the search for an effective cognition-enhancing therapy has so far proved elusive (see page 90). Applicants argue that this reference is irrelevant in light of the examples cited in the specification. However, the working examples do not establish the treatment of age associated impairments in performance on cognitive and memory tasks as a result of the presence of extracellular deposits of amyloid-beta. The examples recited in the specification are not art recognized animal models for the measurement of cognition enhancement as a result of Alzheimer. The working examples in the specification and in the declaration fail to provide the correlation between traumatic brain injury and Alzheimer's. Finally, Applicants have asserted that Applicants are not required to provide guidance or working examples of every possible embodiment of the invention. Applicants are however reminded that the MPEP states that "[p]roof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the

genus as a whole without undue experimentation." M.P.E.P 2164.02. In this case the art indicates undue experimentation for the treatment of neuroprotection and cognitive enhancement as a result of Alzheimer's

The Rejection is Maintained.

Claim Rejections - 35 USC § 102

The rejection of claims 1-7 and 10 rejected under 35 U.S.C. 102(b) as being anticipated by Stadler et al. (FR 1583797) is hereby withdrawn.

New Grounds For Rejection

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 12-17, 20-28, 31-32, 73-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are drawn to a method of providing neuroprotection. However, the claims do not recite to whom such a compound is being administered to. Applicants are requested to amend the claims to recite "A method of providing neuroprotection to a person in need thereof, for time and under conditions to provide neuroprotection, said method . . . "

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can normally be reached on (703)308-2923. The fax phone number of this group is (703) 308-4242.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Anish Gupta

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